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Welcome to ENT Insights

We are excited to share with you highlights of leading-edge procedures and research taking place at the University of Cincinnati Medical Center. Stay informed as we feature new techniques, breakthrough technologies, and innovative approaches our team of highly trained and experienced otolaryngologists and otologists are leading to advance the field.

State-of-the-art Hypoglossal Nerve Stimulation Therapy Offers Option to Traditional Treatment for Obstructive Sleep Apnea

As many as 50% of patients with obstructive sleep apnea (OSA) are unable or unwilling to adhere to ongoing continuous positive airway pressure (CPAP) therapy prescribed for the condition, reports David L. Steward, MD, Professor of Otolaryngology at the University of Cincinnati. Of the available alternative solutions, including oral devices and pharyngeal surgery, none is widely effective.

Hypoglossal nerve stimulation therapy is a recently-approved procedure for CPAP refractory patients, which uses surgical implantation of a pacemaker-like device to stimulate the upper airway via the hypoglossal nerve and improve OSA.

Steward describes how the procedure addresses the primary physiological challenge of OSA, the tongue collapsing during sleep and impeding airflow: “The neurostimulator delivers electrical stimulating pulses to the hypoglossal, or twelfth cranial nerve through the stimulation lead, and the stimulating pulses are synchronized with ventilation detected by the sensing lead. These pulses stimulate the hypoglossal nerve to move the tongue forward.” Currently, the procedure is commercially available only at select high-volume centers, with approval having come after the publication of results from the Stimulation Therapy for Apnea Reduction (STAR) trial in the *New England Journal of Medicine*, which Steward co-authored. In that study, two-thirds of participants responded favorably to the treatment, an improvement on the generally-accepted 50% of patients who benefit from pharyngeal surgery. A follow-up study of 111 of the 126 original participants showed continued efficacy for 80% of patients after 30 months, and additional long-term studies are underway.

Physicians at the University of Cincinnati Medical Center also utilize drug-induced sleep endoscopy to evaluate the pattern of throat collapse in potential candidates, excluding those who display a circumferential pattern of collapse while including those with an anterior/posterior collapse pattern, since the hypoglossal nerve stimulator is designed to move the tongue forward during sleep. However, the role of drug-induced sleep endoscopy in suggesting a method of OSA treatment is still evolving.

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A variety of topical products are available to surgeons to address postsurgical scarring; however, a consensus opinion about treatment superiority has not been reached. David B. Hom, MD, Director, Division of Facial Plastic and Reconstructive Surgery at the University of Cincinnati Medical Center, addressed this issue in the most up-to-date literature review recently published in *Laryngoscope.* Hom adhered the highest clinical evidence, (level 1) investigating the most commonly used agents for scar reduction: silicone gel, paper tape, cyanoacrylates, onion extract (Mederma), and vitamin E. In this paper, the most recent randomized, prospective, and placebo-controlled studies were reviewed.

The article states during early healing of the incision, it should be kept moist, clean, and protected from tension and mobility to encourage epithelial closure. Paper tape and the cyanoacrylates can be applied at this time. After the incision has closed, a scar topical product such as silicone gel can be applied. This review found that silicone gel, paper tape, and cyanoacrylates were beneficial to reduce scarring.

However, the efficacy of other frequently used agents is not supported by level 1 clinical evidence to date. Onion extract gel (Mederma) and Vitamin E, both popular postsurgical scar treatments, did not show improvement in scarring in double-blinded studies. Further investigations are warranted in the treatment duration of these products.

Most studies have investigated single product ingredients. However, since most products contain a combination...
Mechanisms of allergen-specific immunotherapy and the role of regulatory T cells in allergic diseases.

Injectable Medications to Shift the Treatment Paradigm for Middle and Inner Ear Diseases

Increasingly, physicians are treating ear diseases locally via injectable medications rather than systemically, with the goal of avoiding side effects that can accompany oral medication treatments.

Ravi N. Samy, MD, Associate Professor of Otolaryngology at the University of Cincinnati Medical Center, describes the challenge of the eardrum's function of protecting the middle and inner ear limiting access to these areas. One option is intratympanic (IT) injection to gain this access, which can take less than 15 seconds and utilizes exceedingly small needles, thus improving patients' willingness to undergo the procedure. These injections can be used to treat a variety of problems from vertigo to tinnitus to sudden hearing loss to Ménière's disease.

Otonomy, Inc. is currently conducting a study of a sustained-exposure injectable formulation of the steroid dexamethasone for the treatment of Ménière's disease in which the University of Cincinnati Medical Center is participating. This study, titled “A Prospective, Randomized, Double-blind, Placebo-controlled, Multicenter, Phase 2b Study of OTO-104 Given as a Single Intratympanic Injection in Subjects with Unilateral Ménière's Disease,” uses a primary endpoint of reduction in vertigo frequency as a measure of efficacy of the injectable steroid compound, called OTO-104, over four months following a single administration. Other outcomes include tinnitus severity and its impact on daily activities as reported via a patient diary and questionnaire, and safety by monitoring adverse events and the use of otoscopic exams, audiometry, Word Recognition Score and tympanometry.

The use of injectable steroids instead of invasive surgery to treat Ménière's disease would eliminate the risks associated with surgery including those related to the use of anesthesia and other surgical complications, as well as result in significant cost savings. Furthermore, Samy comments on the potential for broader use: “The hope is that this compound could prove effective not only for Ménière's disease, but also for sudden hearing loss where physicians routinely use oral and injectable steroids today. Steroids can increase blood supply to the inner ear, reduce inflammation, and potentially recover hearing.” Samy also foresees their work with cochlear implantation being combined with injectable steroid use to further improve patient outcomes. He concludes, “It is an exciting time. They say the 21st century will be an era marked by focus on the brain, and I think that's absolutely correct. With the ear being so connected to the brain, much of what we do affects neurological function, and vice versa, as well as enhancing quality of life.”

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of ingredients, future studies should be undertaken to identify their combined effects as a whole. Hom stresses that a set of clear, consistent objective criteria is needed to evaluate scars in terms of width, thickness, contour, and color, as scar maturity occurs over six months.

This is a significant area of interest for Hom, as he is currently co-editing a multidisciplinary book on facial scar treatment with Dr. Regan Thomas from Chicago. This topic is a natural progression from his previous book, Essential Tissue Healing of the Face and Neck, which was favorably reviewed by the Journal of the American Medical Association.2

Scar reduction techniques are likely to evolve in the future, with the administration of cytokines prophylactically prior to surgery showing promise. Hom describes the potential for the treatment: “This would be similar to what we currently do with antibiotics in patients in clean-contaminated cases by administering antibiotics prior to surgery in order to reduce infection. In a similar scenario, the administration of TGF beta-3 given preoperatively may reduce postsurgical scarring from developing in patients who are at higher risk for scarring.”

References:

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Steward was a lead investigator of the STAR trial, participating in the study design and planning for the trial. Steward views hypoglossal nerve stimulation as an exciting new development in the treatment of OSA, especially given the fact that traditional pharyngeal surgery is associated with a high degree of postoperative pain and swallowing difficulty for several weeks after the procedure. Not only is hypoglossal nerve stimulation associated with better outcomes than surgical uvulopalatopharyngoplasty, early postoperative morbidity has been seen to be significantly reduced as well. For OSA patients who cannot or do not adhere to CPAP therapy, hypoglossal nerve stimulation may be a useful alternative.


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Standardized dosing of sublingual immunotherapy remains an area of intense study, and many variables influence efficacy of allergy immunotherapy for subcutaneous as well as sublingual administration. Read more on this topic and much more at ENTInsights.com.
Sublingual immunotherapy (SLIT) involves dosing the allergen under the tongue of the patient in controlled amounts, often over a period of several years, in order to increase tolerance to a particular allergen and diminish symptoms brought on by exposure to that allergen. SLIT using aqueous drops has been used sporadically in the United States since its discovery by French Hansel, MD, in St. Louis in the 1920s. For the last 30 years, it has been in wider clinical use in numerous countries in Europe and Australasia to treat allergies. A surge of research regarding efficacy and safety in the last five to ten years led to United States Food & Drug Administration (FDA) approval of the soluble tablet formulation in 2014. The University of Cincinnati Medical Center Otolaryngic Allergy Program staff is well-prepared to use this newly-approved technique due to the extensive training they have received.

Following a rigorous allergy treatment algorithm, the process begins with a detailed clinical history of the patient, combined with skin and/or serum testing to determine specific elevations in immunoglobulin E (IgE), indicating allergen sensitivities and their intensity. Alfred Sassler, DO, Associate Professor of Otolaryngology, directs the Allergy Program at the University of Cincinnati Medical Center, and trains the clinical staff personally. He is one of very few physicians in the region who have demonstrated the knowledge and experience to attain the status of Fellow in the American Academy of Otolaryngic Allergy (AAOA). He adds, "All of our allergy nurses attend an intensive training program conducted by the AAOA. Their participation is not required by the profession, but we believe that better-informed and trained staff can better treat our patients." The multi-day AAOA training program centers around clinical issues related to the care of allergy/immunology and inflammatory diseases of the airways and systems related to the head and neck. It is structured as a continuing education course for physicians (otolaryngologists and others), PA/NPs, and allied health staff who support their physicians in the management of allergic 

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